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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/000,542	04/15/2010	7,591,844 B2	CRDS-0116	8264

45511 7590 02/27/2015

Baker & Hostetler LLP
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EXAMINER
HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
02/27/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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95/000,552	06/14/2010	7591844	01035.0068-00000	9463

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC SCIMED and ABBOTT LABORATORIES
Requester and Respondent

v.

Patent of
CORDIS CORP., A JOHNSON & JOHNSON CO., and WYETH, A PFIZER CO.
Patent Owner and Appellant

Appeal 2014-008135
Reexamination Control 95/000,542 and 95/000,552
Patent 7,591,844 B2
Technology Center 3900

Before ROMULO H. DELMENDO, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal by Patent Owner from the Patent Examiner's final rejection of claims 1–17 and 19–23 as obvious under 35 U.S.C. § 103 in the above-identified merged *inter partes* reexaminations of United States Patent

7,591,844 B2. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315 (pre-AIA). We affirm.

BACKGROUND

The patent in dispute in this appeal is US 7,591,844 B2 ("the '844 patent") which issued September 22, 2009. The real parties in interest and assignees are Cordis Corporation, a Johnson & Johnson company, and Wyeth, a Pfizer company ("Patent Owner"). Appeal Br. 1 (October 17, 2012). Patent Owner appeals the Examiner's final rejection of claims 1–17 and 19–23.

A request for *inter partes* reexamination of the '844 patent was filed April 15, 2010 by Boston Scientific SCIMED, Inc. under 35 U.S.C. §§ 311–318 and 37 C.F.R. §§ 1.902–1.997. A second request for *inter partes* reexamination was filed June 14, 2010 by Abbott Laboratories. The reexaminations were merged into a single proceeding. Decision, *Sua Sponte* Merging *inter partes* proceedings (Nov. 26, 2010).

An oral hearing was held January 21, 2015. A transcript of the hearing has been entered into the record ("Hearing Tr.").

The claimed subject matter of the '844 patent relates to a device for intraluminal implantation in a vessel comprising a "balloon expandable stent" and a "pharmaceutical agent-containing coating." The coating comprises vinylidinefluoride (VDF) copolymerized with hexafluoropropylene (HFP) in a weight percent ratio of 85:15. According to the '844 patent, transluminal angioplasty can be used to increase blood flow through a blocked artery by widening the artery through the use of an expandable balloon stent. '844, cols. 1–2. Although angioplasty has a short-term immediate benefit, the benefit is not always

lasting."Upon pressure expansion of an intracoronary balloon catheter during angioplasty, smooth muscle cells within the vessel wall become injured, initiating a thrombotic and inflammatory response." *Id*. at col. 2, ll. 10–13. As a result, the vascular wall can narrow again in a process called "restenosis." *Id*. at col. 1, ll. 46–51; col. 2, ll. 33–35. The '844 patent teaches that stent coatings containing a pharmaceutical agents may be used to reduced restenosis. *Id*. at col. 4, ll. 43–54. The patent teaches in the "Background of the Invention" that "[s]tents with coatings made from polyvinylidenefluoride [VDF] homopolymers and containing pharmaceutical/therapeutic agents or drugs for release have been suggested." '844 patent, col. 5, ll. 4–6.

CLAIM 1

Independent claims 1 and 19 are the only independent claims involved in the appeal. Claim 1 is drawn to a device and claim 19 to a method of preparing a device. Claim 1 is representative and reads as follows (abbreviations within braces added):

> 1. A device for intraluminal implantation in a vessel comprising a balloon-expandable stent and a pharmaceutical agent-containing coating, said coating comprising a biocompatible polyfluoro copolymer that comprises about eighty-five weight percent vinylidinefluoride {VDF} copolymerized with about fifteen weight percent hexafluoropropylene {HFP} and at least one pharmaceutical agent intermixed with said copolymer, wherein said coating has not been subjected to a maximum temperature greater than 60° C during the coating process or afterward, thereby providing an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent.

REJECTIONS

The claims stand rejected by the Examiner over 33 different combinations of publications. Appeal Br. 4–6; Abbott Respondent Br. 1. Each of the rejections of independent claims 1 and 19 is based on substantially the same factual underpinnings, but relies on different publications for the same set of facts. Rather than addressing each ground separately, Patent Owner has focused its arguments on the factual basis of the rejections, grouping their arguments together for the various grounds of rejection of the independent claims. The rejections of the dependent claims were not argued separately.

For clarity, the table below summarizes the ten different grounds of rejection which involve independent claims 1 and 19. The rejections which involve dependent claims only have not been listed since they were not separately argued. There are three main groups of publications: 1) Tuch,[1] Wright, Kamath, and Patent Owner's Admissions, each of which is cited for teaching a stent coated with a polymer comprising a therapeutic agent: 2) Tu[2] and Lilenfeld, each of which is cited for teaching of a medical device comprising VDF:HFP; and 3) Lo[3], Wille, and Modern Fluoropolymer, each of which is cited for teaching of VDF:HFP in the claimed wt% of 85:15.

[1] Tuch	US 5,824,048	Oct. 20, 1998
[2] Tu et al. (Tu)	US 4,816,339	Mar. 28, 1989
[3] Lo	US 3,178,399	Apr. 13, 1965

	1	2	3	4	5	6	7	8	9	10
	1-17, 19-23	1-15,19-21	1-15, 19-21	1-15, 19-21	1-15,19-21	1-17, 19-23	1-17,19-23	1,2,8,19,20	1,2,8,19,20	1,2,8,19,20
Tuch		Y	Y	Y	Y					
Wright						Y	Y			
Kamath								Y	Y	Y
Pat. Admission	Y									
Tu	Y	Y		Y	Y	Y	Y	Y	Y	Y
Lilenfeld			Y							
Lo	Y	Y				Y		Y		
Wille				Y			Y		Y	
Modern Fluoropolymers					Y					Y

The table above shows the ten different grounds over the independent claims. Because the rejections were argued together, we have focused on the rejection based on Tuch, Tu, and Lo (rejection 2, above), and have not reached rejections 1 and 3–10, although as recognized by Patent Owner, similar rationale would apply.

In addition to the prior art publications, the following declarations have been cited as evidence:

First Declaration by Antonios G. Mikos, Ph.D ("First Mikos Decl.") dated Aug. 27, 2010. Dr. Mikos was a Professor of Bioengineering and Chemical and Biomolecular Engineering in the Departments of Bioengineering and Chemical and Biomolecular Engineering at Rice University at the time the declaration was executed. First Mikos Decl. ¶ 1. Dr. Mikos testified that he has expertise in the synthesis, fabrication and application of biomaterials, specifically polymers, for medical applications, including cardiovascular applications. *Id*. at ¶ 3. Dr. Mikos testified on behalf of the Patent Owner.

2012 Declaration by Michael N. Helmus, Ph.D. ("2012 Helmus Decl.") dated March 30, 2012. Dr. Helmus testified that he is an expert in biomaterials, biocompatibility, and biomaterial databases for medical device applications and currently works as a consult in the field of medical devices. Dr. Helmus testified on behalf of Abbott.

SCOPE AND CONTENT OF THE PRIOR ART[4]

Tuch

Tuch1. Tuch describes an intravascular stent that has a coating on its tissue-contacting surface which comprises a polymer and therapeutic substance. Tuch, col. 2, ll. 36–38.

Tuch2. Tuch teaches that the stent can be of any design, including self-expanding and balloon-expandable types. *Id*. at col. 4, ll. 10–13.

Tuch3. Tuch discloses that the polymer must be biocompatible and minimize irritation to the vessel wall when the stent is implanted. *Id*. at col. 5, ll. 14–16.

Tuch4. Tuch also teaches that the polymer may be either biostable or bioabsorbable. *Id*. at col. 5, ll. 15–16.

Tuch5. Tuch describes "biostable polymers with a relatively low chronic tissue response." *Id*. at col. 5, ll. 33–34.

Tuch6. The list of the biostable polymers includes "vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride [VDF] and polyvinylidene chloride." *Id*. at col. 5, ll. 38–42.

Tuch7. Tuch teaches that during implantation of an expandable stent, the delivery balloon expands and deforms the stent elements and coating. *Id*. at col. 7, ll. 9–11.

[4] Factual considerations that underlie the obviousness inquiry include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Tuch8. When the polymeric overlayer on the stent is uniform and "made with materials which have little elasticity," Tuch teaches that "the overlayer can sustain significant cracking during such deformation" and the "cracks can then act as channels for more rapid elution of drugs from the drug-rich base coating." *Id*. at col. 7, ll. 11–15.

Tuch9. Tuch teaches that "cracking of the overlayer can be reduced and drug elution times increased by providing a porous overlayer on the stent." *Id*. at col. 7, ll. 16–18.

Tuch10. Tuch teaches that the coating should be "resilient"[5] for stent expansion: "The inclusion of a polymer in intimate contact with a drug on the stent allows the drug to be retained on the stent in a resilient matrix during expansion of the stent . . ." *Id.* at 2:42–46. In context, Tuch uses the term "resilient" to have its ordinary meaning, which is to be "able to return to an original shape after being pulled, stretched, pressed, bent, etc.," a synonym being "elastic."

Tu

Tu1. Tu describes implantable biomedical devices formed with layers of polytetrafluoroethylene, polytetrafluoroethylene/elastomer, and elastomer. Tu, col 2, ll. 7–37.

Tu2. Tu teaches that its invention relates to various types of implantable bioomedical devices, including heart valve leaflets, and the invention particularly relates to vascular grafts. *Id*. at col. 1, ll. 27–32; col. 2, ll. 36–40.

[5] "Resilient" means "able to return to an original shape after being pulled, stretched, pressed, bent, etc." and a synonym is "elastic." http://www.merriam-webster.com/dictionary/resilient (accessed Jan. 28, 2015).

Tu3. Tu discloses a list of compounds used to prepare the elastomer. *Id*. at col. 2, ll. 20–30. Polyvinylidene fluoride co-hexafluoropropylene (VDF:HFP) is first on the list. *Id*. at col. 2, ll. 23–24.

Tu4. Tu teaches that the elastomer provides elasticity and strength. *Id*. at col. 3, ll. 40–44, 64.

Tu5. According to Tu, the "elastomer solution may optionally contain therapeutic agents including but not limited to antibiotic and/or hemostatic substances." *Id*. at col. 8, ll. 45–47.

Tu6. Tu teaches that the implantable material made of polytetrafluoroethylene and elastomer is biologically compatible. Id. at col. 2, ll. 11–19, 31; col. 3, l.

Lo

Lo1. Lo describes copolymers of vinylidene fluoride (VDF) and hexafluoropropene (HFP) which have flexibility, elasticity, and extensibility. Lo, col. 2, ll. 33–36, 47, and 56–58.

Lo2. Figure 1 of Lo shows an increase of tensile PSIG and reversible elongation from about 86 mol percent to a maximum of about 94 mol percent with a copolymer made of vinylidene fluoride and hexafluropropene.

Lo3. Lo teaches that "[a]bove about 94 mol percent vinylidene fluoride (i.e. less than 6 mol percent hexafluoropropene) the copolymer is essentially crystalline in nature and the reversible elongation decreases rapidly." Lo, col. 9, ll. 33–36.

Lo4. The Examiner found that "copolymers with an optimal combination of tensile strength and reverse elongation are achieved at 93 mol % VDF, corresponding to a VDF/HFP wt% ratio of 85:15 (Fig. 1; col. 9, lines 15–27)."

RAN 14. Dr. Mikos in his declaration acknowledged that "Lo describes VDF/HFP coatings having VDF:HFP weight percent of 85: 15." First Mikos Decl. ¶ 41.

Le Morel[6]

LeM1. LeMorel teaches implants such as stents. LeMorel 2:4–15.

LeM2. Le Morel teaches that the substrate of the implant can be a polymer, and specifically identifies copolymers of vinylidene fluoride and hexafluorpropylene among a list. *Id.* at 3:1–5 and 18–19.

LeM3. Le Morel teaches in the case of stents, a fluorinated polymer is advantageous. *Id.* at 4:4–10.

DIFFERENCES BETWEEN THE CLAIMED INVENTION AND THE PRIOR ART

The Examiner found that Tuch describes a balloon-expandable stent having a coating containing a therapeutic agent, meeting the claimed limitation of "a balloon-expandable stent and a pharmaceutical agent-containing coating." RAN 13-14; Tuch1–2, 7. The Examiner found that the coating may be formed with VDF. RAN 14; Tuch6. The Examiner found that Tuch does not describe a coating "that comprises about eighty-five weight percent vinylidinefluoride [VDF] copolymerized with about fifteen weight percent hexafluoropropylene [HFP]," but found that Lo describes such a copolymer coating and its advantages with respect tensile strength and reversible elongation. RAN 14; Lo1–4. Furthermore, the

[6] Le Morel et al. (Le Morel or LeM) FR 2,785,812 Nov. 16, 1998. Citations to translation of record.

Examiner found that Tu demonstrates the biocompatibility of VDF/HFP polymers and that such copolymers can contain therapeutic substances. RAN 14; Tu5.

Based on the teachings of Lo and Tu, the Examiner determined it would have been obvious to one of ordinary skill in the art to have replaced "Tuch's crystalline VDF homopolymer with the partially crystalline copolymers having a VDF/HFP wt % ratio of about 85:15 (as recited in [device] claim 1 and method claim 19) . . . to arrive [at] the instant invention." RAN 14–15. The Examiner's rationale was that a person of ordinary skill in the art would have understood that VDF/HFP is advantageous as compared to VDF homopolymers and has optimal tensile strength and reversible elongation at VDF/HFP wt% ratio of 85:15 as shown by Lo. *Id*. at 14.

Discussion

Patent Owner contends that the Examiner erred in combining the publications to have arrived at the claimed invention. Specifically, Patent Owner argues that one of ordinary skill in the art reading Tuch would not have had reason to choose polymers from publications other than Tuch because Tuch did not identify a problem with its polymers used for its drug coating layer. Appeal Br. 16. Patent Owner also argues that it is improper to combine Tu's teachings with those of Tuch. *Id*. at 17.

Choice of VDF:HFP

It is unnecessary that Tuch disclose any shortcomings in its list of polymers for the ordinary skilled worker to have found it obvious to have employed an alternative polymer for its coating since it is obvious to use a prior art element for

its established function. As held in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007), in making an obviousness determination, it must be asked "whether the improvement is more than the predictable use of prior art elements according to their established functions." Thus, even if Tuch did not disclose a problem with its polymers, one of ordinary skill in the art would have found it obvious to have employed the known polymers of Tu and Lo for their known and expected properties. As argued by Abbott, Abbott Respondent Br. 12, the reason to combine could be provided by the "normal desire of scientists or artisans to improve upon what is already generally known." *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003).

In addition to this, Tuch does not limit its polymers to those specifically disclosed. Tuch teaches using "vinyl halide polymers and copolymers," and specifically discloses "polyvinylidene halides, such as polyvinylidene fluoride." Tuch6. This disclosure, while mentioning a specific polyvinylidene halide, also includes broader classes ("vinyl halides" and "polyvinylidene halides"), including copolymers, which would have reasonably suggested that additional polymers, outside those specifically described in Tuch, would be useful as Tuch's polymer coating comprising a therapeutic substance.

To support their position about the unobviousness of using polymers other than those disclosed in Tuch, Patent Owner cites *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342,1370–71 (Fed. Cir. 2012).

> As in *Kinetic Concepts, Inc.* 688 F.3d at 1369, a case in which the Federal Circuit overturned a prior finding of obviousness, the record here "is devoid of any reason someone would combine [the cited] references." Where, as here, each device that the references describe "independently operates effectively," a person having ordinary skill in

> the art "would have no reason" to combine the reference'' respective teachings. *Id*.

Appeal Br. 17. *See* also Rebuttal Br. 3.

In *Kinetic*, the issue was whether to combine publications which "both . . . independently accomplish similar functions, namely, draining fluids." *Kinetic Concepts, Inc*. 688 F.3d at 1369. One set of publications involved negative pressure to drain wounds. *Id*. at 1362-1363. The other set of publications disclosed a different type of wound drainage system. *Id*. at 1365. The obviousness rejection was predicated on combining the two sets of publications to meet a limitation in the claim of using negative pressure to treat a wound, where wound treatment had not been found to be present in the negative pressure publications. *Id*. at 1361, 1363. Because each publication was complete in teaching a wound drainage method, and there was no teaching that negative pressure could be used to treat wounds, the court found "a person having ordinary skill in the art, who was merely seeking to create a better device to drain fluids from a wound, would have no reason to combine the features of both devices into a single device." *Id*. at 1369.

The facts of this case are clearly distinguishable. Tuch teaches various polymer coatings for its stent, including broad classes that encompass unnamed species. Tu was cited in the rejection for teaching polymers suitable for Tuch's stent coating. The reason to consult Tu is because Tuch's list of polymers is clearly not exhaustive in view of Tuch's description of broad classes of polymers, such as vinyl halide polymers and copolymers, and polyvinylidene halides. Tuch6. Tuch also uses the transitional phrase "such as" in prefacing the list of biostable polymers and in reciting specific examples of the broader classes, indicating that Tuch did not confine the skilled worker to the explicit list, but contemplated

polymers outside of it. ("Also, biostable polymers with a relatively low chronic tissue response such as . . . and other polymers could also be used if they can be dissolved and cured or polymerized on the stent such as . . . vinyl halide polymers and copolymers, such as . . . " Tuch, col. 5, ll. 33–39).

Patent Owner argues that Tuch recites a long laundry list of polymers and therefore would not have directed the skilled worker to the specifically claimed polymers. Appeal Br. 24. First Mikos Decl. ¶¶ 52–56.

The fact that "vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride [VDF] and polyvinylidene chloride" appear in a longer list (Tuch6) would not have dissuaded one of ordinary skill from choosing VDF copolymers. The list recited in Tuch is of polymers that Tuch considered useful for its stent coating and therefore is a disclosure of each and every one for a stent coating. There does not have to be a working example of vinyl halide polymer copolymer, polyvinylidene halide, or VDF, as alleged by Dr. Mikos (First Mikos Decl. ¶ 143) for one of ordinary skill in the art to have recognized such compounds as useful for a polymer coating since Tuch expressly describes their use for this purpose. Tuch6.

Furthermore, Patent Owner admitted in the "Background" of the '844 patent that "[s]tents with coatings made from polyvinylidenefluoride homopolymers and containing pharmaceutical/therapeutic agents or drugs for release have been suggested." '844 patent, col. 5, ll. 4–6. *See* also "Preexamination Search Statement and Accelerated Examination Support Document" 12 ("AESD"; filed Nov. 16, 2007 in the application that led to the '844 patent) identifying the latter statement as prior art.

Dr. Mikos attempts to distinguish Tuch because Tuch describe a porous overlayer of polymer to control drug release. First Mikos Decl. ¶ 144. However, the claim does not exclude such a porous layer made of VDF:HFP.

Patent Owner also argues that the stent coating in Tuch is in contact with the vessel wall lining and in contact with blood, while in Tu, the graft's inner surface which contacts the blood lacks the elastomer. Appeal Br. 23. While this might be the case, Tu teaches that it's the polytetrafluoroethylene/elastomer which can be used generally in other medical devices, such as a heart valve leaflet that could be in contact with blood. Tu2.

Is there an adequate reason to have combined Tuch and Tu?

Patent Owner argues that the record is devoid of reason to have combined Tuch and Tu. Appeal Br. 17. Patent Owner also argues that Tu relates to vascular grafts and therefore is not relevant to Tuch.[7] *Id*. at 18:1–2.

A preponderance of the evidence does not support Patent Owner's position that the record lacks a reason to combine Tuch with Tu.

First, Tu is not limited to vascular grafts, but clearly teaches that its polymers are useful for various types of implantable devices. Tu2. While vascular grafts are preferred, such preference does not negate the broader teaching.

Second, Tu's polyvinylidene fluoride co-hexafluoropropylene has the properties described in Tuch as useful for its stent coating. These properties are discussed below:

1) Tuch's polymers are biocompatible as they are in Tu. Tuch3; Tu6.

[7] Taking a contrary position, in the AESD filed in the application that led to the '844 patent, Patent Owner characterized Tu (US 5,061,276) as one of the "most closely related" prior art references. AESD 6. Abbott Respondent Br. 15.

2) Tuch teaches elastic polymers are beneficial for coatings in expandable stents. Tuch8, 10. Tu's elastomers are elastic. Tu4.

Patent Owner contends that elasticity would not have been a factor in choosing a polymer coating for Tuch's stent. Appeal Br. 18–19. However, Tuch teaches that, when the stent delivery balloon expands, the stent coating can deform. Tuch7. When materials are used for the polymers which "have little elasticity," the polymer overlayer can crack during the expansion and result in rapid drug elution. Tuch8. Tuch teaches one way to reduce the cracking. Tuch9. Since Tuch teaches a problem with cracking when materials having little elasticity are utilized in the polymer layer, one of ordinary skill in the art would have reasonably sought materials with high elasticity to avoid the problem when the stent is expanded.

Furthermore, Tuch teaches that using a resilient matrix during expansion of the stent is beneficial for drug retention. Tuch10. Resilient is a synonym for elastic. Fn. 5. *See* also 2012 Helmus Decl. ¶ 6 for further evidence of the desirability of an elastic polymer. Tu teaches elastomers that provide elasticity and strength. Tu4.

Dr. Mikos testified that the "physical and mechanical properties that are important for the Tu vascular grafts . . . are very different from the physical and mechanical properties that are important for polymer coatings used on balloon expandable stents [as in Tuch]." First Mikos Decl. ¶ 43. Dr. Mikos identifies elasticity as important in vascular grafts. *Id*. at ¶ 44. Dr. Mikos, however, did not explain how elasticity is distinguishable from the ability of a polymer to be elongated or deformed before breaking which he identified as an "important property" of a stent polymer coating. *Id*. at ¶¶ 46, 147. That is, while Tu's graft may have a different purpose than Tuch's stent, Dr. Mikos admits that a stent

coating must be resilient (resist deformation before breaking) which is the same property that Dr, Mikos identifies as important in vascular grafts. Consequently, Dr. Mikos's testimony about the lack of reason to combine Tuch and Tu is not supported by persuasive factual evidence.

3) Tuch teaches that polyvinylidene fluoride is a useful polymer for its coating comprising a therapeutic substance. Tuch1, 6. The first elastomer on Tu's list is a copolymer comprising polyvinylidene fluoride and hexafluoropropylene (VDF:HFP). Tu3. The obviousness of choosing VDF:HFP as a stent coating is further evidenced by Le Morel who describes the copolymer as coating on a stent. LeM1–3.

4) Tuch teaches a polymer coating that delivers a therapeutic substance. Tuch1. Tu also teaches that its elastomer can contain therapeutic agents. Tu5.

Summary

In sum, a preponderance of the evidence supports the determination it would have been obvious to have selected VDF:HFP from Tu as the polymer coating in Tuch. Contrary to Patent Owner's statement that it would have been a scavenger hunt to find VDF:HFP (Hearing Tr. 4:6–11), VDF:HFP is disclosed by Tu as a useful elastomer for an implantable medical device and Tu's elastomers have the properties described by Tuch as advantageous in a stent, which is an example of an implantable device.

Proportion of VDF and HFP

As far as the 85:15 copolymer of VDF and HFP recited in the claims, Lo teaches that a 85:15 copolymer is advantageous with respect to flexibility,

elasticity, extensibility, tensile strength, and reverse elongation. Lo1–4; RAN 14. One of ordinary skill in the art would have been motivated to have used Lo's polymer having these advantageous properties as the coating in Tuch because Tuch teaches a problem with coatings with low elasticity (Tuch8-9).

Because VDF:HFP is expressly described by Tu as useful for an implantable medical device (Tu2), the skilled worker would have reasonably consulted Lo to determine the optimal concentrations for each component, even if Lo does not teach the use of VDF:HFP for medical implants. Patent Owner's argument that Lo's uses are industrial and therefore not pertinent to stents (Appeal Br. 24; First Mikos Decl. ¶¶ 41–42) is unavailing since Lo was cited for teaching the properties of VDF:HFP which had been taught to be useful by Tu in a medical device.

Patent Owner's argument that VDF:HFP is not described as a carrier for a drug has little merit. Appeal Br. 25. As mentioned, Tu teaches that its elastomer may contain therapeutic agents. Tu5.

SECONDARY CONSIDERATIONS

Factual considerations that underlie the obviousness inquiry include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations. *Graham.*, 383 U.S. at 17-18. Relevant secondary considerations include commercial success, long-felt but unsolved needs, failure of others, praise, and unexpected results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007); *Institut Pasteur & Universite Pierre et Marie Curie v. Focarino*, 738 F.3d 1337, 1344 (Fed. Cir. 2013); *In re Soni*, 54 F.3d 746 (Fed. Cir. 1995). Secondary considerations are "not just a cumulative or confirmatory part of the obviousness

calculus but constitute [] independent evidence of nonobviousness . . . [and] enable [] the court to avert the trap of hindsight." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013) (internal quotation marks and citations omitted). "This objective evidence must be 'considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.'" *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) (internal citations omitted).

Patent Owner contends that the Examiner failed to credit the evidence of nonobviousness of the claimed invention. Appeal Br. 9–10. As evidence, Patent Owner cited studies performed with the Xience V stent. Patent Owner asserts that Xience V is a stent sold by Abbott Laboratories that "employs Solef® 21508 (Patent Owner's Response to ACP, at pg. 16), a VDF:HFP copolymer that comprises about 85% VDF and about 15% HFP." Appeal Br. 11.

Copying

Patent Owner states that the invention of the '844 Patent has been copied and adopted by others in the industry, including by Abbott (Xience V stent) and by Boston Scientific (Promus stent). Appeal Br. 9–10. As evidence, Patent Owner cites to paragraph 224 of the first Mikos declaration. However, paragraph 224 merely alleges copying by Abbott and Boston Scientific without factual evidence or analysis to support this statement. RAN 71. Consequently, without adequate evidence that Abbott and Boston Scientific copied the claimed invention, we give this argument little weight.

Commercial success

Patent Owner contends that commercial success of the claimed invention is demonstrated by the statement in Abbott's 2008 Form 10K that "'Xience V became the market-leading drug eluting stent in the U.S. in the fourth quarter of 2008,' within just three months of FDA approval" and Dr. Mikos's statement that the "PVDF-HFP coating used in the Xience V stent is an important factor in the clinical success of the Xience V stent, and therefore also in the commercial success of the Xience V and Promus stents. First Mikos Decl. ¶ 227. Patent Owner further cited Abbott's fact sheet on the Xience V stent which represented that "the composition of the polymer coating" in the Xience V stent "is important in overall clinical safety and efficacy outcomes." Appeal Br. 11 (fn. 4). Patent Owner also cited evidence that Xience's thin, nonreactive polymer accounted for its success. *Id*. at 12 (fn. 5).

For evidence of secondary considerations to be accorded substantial weight, there must be a nexus between the claimed invention and what is relied upon as the secondary consideration. *In re GPAC*, Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995). A nexus is established when the secondary consideration is attributed to a feature of the claimed invention. *Ormco Corp. v. Align Tech*., Inc., 463 F.3d 1299, 1311–12.

In this case, even if there is evidence that the coating is one factor that contributed to the success of Xience, there is additional evidence that the drug and stent material are also important reasons for its success. Neither the drug nor the stent material is recited in claims 1 and 19. In this regard, as noted by the Examiner (RAN 73), Ex. 10 describes the drug and stent frame as reasons for the success of Xience V:

> Assessing why second-generation DES such as Xience may be superior to earlier-generation stents, the editorialists point out that they may differ on many fronts: the antiproliferative agent (in this case everolimus vs. paclitaxel), the polymer layer (Xience's is biocompatible), and stent frame (flexible cobalt-chromium vs. stainless steel). For example, improved stent design may result in better stent apposition and endothelialization as well as reduced platelet aggregation and thrombus formation. However, since the relative contribution of each of these elements to the enhanced performance of Xience is unknown, the study results are not necessarily applicable to other everolimus-eluting stents, Drs. Lange and Hillis caution.

Ex. 10

Similarly, Exhibit 9 states:

> Everolimus is a more potent drug than those used in the first-generation coated stents and also is contained in a thin, inert polymer that is less likely to cause inflammation, Stone said. The Xience stent itself is also thinner than the previous devices, he added.

Patent Owner represented that Dr. Stone had attributed Xience's commercial success to the polymer coating. Appeal Br. 12 (fn. 5). However, in theheart.org it was reported that Dr. Stone highlighted several reasons for the success of Xience, and not only the polymer coating as indicated by Patent Owner:

> Stone, who first presented the SPIRIT III results at the TCT 2007 meeting, told heartwire that two-year results will be presented at the upcoming EuroPCR meeting in Barcelona. He highlighted design characteristics of the Xience—**thinner struts; a thin, nonreactive polymer; and a drug with similar potency to sirolimus**—as key reasons not only for the reduced late loss at nine months, fewer repeat procedures at one year, and fewer procedural MIs, but also as factors that may ensure the stent also performs better over time.

theheart.org (emphasis added).

Thus, it has not been established that the claimed polymer in the 85:15 wt% ratio is responsible for the asserted success of the claimed invention, rather than

the drug or the stent material—both which are unclaimed features. Accordingly, the preponderance of the evidence does not support a nexus between commercial success and the merits of the claimed invention ("For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *GPAC*, 57 F.3d at 1580).

Unexpected results

A showing of "unexpected results" can be used to demonstrate the non-obviousness of the claimed invention. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) ("One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of 'unexpected results,' *i.e.*, to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected."). Those results must be "surprising or unexpected" to one of ordinary skill in the art when considered in the context of the closest prior art. *Soni*, 54 F.3d at 750; *Iron Grip Barbell Co., Inc. v. USA Sports, Inc*., 392 F.3d 1317, 1322 (Fed. Cir. 2004) (A showing of "new and unexpected results" must be "relative to prior art."); *In re Baxter Travenol Labs*., 952 F.2d 388, 392 (Fed. Cir. 1991) ("[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art"). To establish unexpected results, the claimed subject matter must be compared with the closest prior art. *Baxter*, 952 F.2d at 392.

Citing paragraph 25 of Dr. Mikos's first declaration, Patent Owner contends that "the PVDF-HFP coated Xience V stent is more thromboresistant (*i.e.,* shows greater tendency to reduce thrombus formation) than other drug-eluting stent

coatings." Appeal Br. 12. Patent Owner also contends that "numerous clinicians have also emphasized that the PVDF-HFP polymer used in the Xience V stent shows unexpectedly less inflammation," again citing to the Mikos declaration. *Id.*

Paragraph 227 of the Mikos declaration refers to Abbott's data in Exhibits 7 and 8. Exhibit 7 is undated. Exhibit 7 at ABT046618 shows that the weight of thrombus adhered to the stent for Xience V was less than for the Cypher, Endeavor, and Taxus Liberté stents. ABT046619 shows that Xience V had lower thrombus adherence "due to smooth coating integrity and hemocompatability of the XIENCE V Fluoropolymer" as compared to the Vision stent.

Dr. Mikos did not fully describe the coatings, stent materials, or therapeutic agents utilized in the stents to which the performance of Xience V was compared. Cypher comprises the drug sirolimus combined with a polymer blend of two non-erodible polymers, polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA), to form the basecoat. First Mikos Decl. ¶ 24. To establish unexpected results, the comparison must be against the closest prior art. *Baxter*, 952 F.2d at 392; *Iron Grip Barbell Co.*, 392 F.3d at 1322. Dr. Mikos did not establish that the coating on Cypher constitutes the closest prior art.

In addition to this, Dr. Mikos did not provide evidence that the purported improved results for Xience V was due to a claimed feature, rather than an unclaimed feature, such as the drug or stent material. *Ormco Corp,* 463 F.3d at 1311–12. Dr. Mikos also did not state the results would have been unexpected or surprising to one of ordinary skill in the art. *Soni*, 54 F.3d at 750.

Exhibit 8 was also cited by Dr. Mikos as evidence of unexpected results. Exhibit 8 is undated. Dr. Mikos cited page 28 of Exhibit 8. This page shoes that the average thrombus weight for Xience was less than for "Vision BMS." "BMS"

is a bare metal stent. Ex. 8, p. 28. The comparison therefore does not appear to be with the closest prior art since Tuch describes coated stents and Vision BMS is bare metal. Tuch1, Tuch3–6. *Baxter*, 952 F.2d at 392.

Dr. Mikos further testified in his written declaration that "numerous clinicians have also emphasized that the PVDF-HFP polymer used in the Xience V stent shows unexpectedly less inflammation." First Mikos Decl. ¶ 228. As evidence, Dr. Mikos cited Exhibits 9 and 10.

Exhibit 9 is a news article. The article mentions that Xience V is "less likely to cause inflammation." Exhibit 10 is also a news article. The article states:

> In a telephone interview with TCTMD, Robert S. Schwartz, MD, of the Minneapolis Heart Institute Foundation (Minneapolis, MN), underlined the role of the polymer in differentiating between the stent generations, saying that Taxus' older polymer was more likely to induce inflammation.

This evidence is not persuasive since it does not establish that the reduction in inflammation observed with Xience V is in comparison with the closest prior art as required under *Baxter*, 952 F.2d at 392. Rather, it appears the news articles are reporting that Xience's polymer is less inflammatory than the polymers on existing stents. Patent Owner has not provided sufficient testimony that this reduced inflammation would have been unexpected by one of ordinary skill in the art in comparison to the polymers described in Tuch, for example, which teaches stents with polymer coatings, including a homopolymer of VDF (Tuch6).

Consequently, the evidence does not support Dr. Mikos's opinion in paragraph 228 about unexpected results associated with the claimed polymer.

Industry praise

Patent Owner states that there "has been industry praise for Xience V that is attributable to the claimed invention." Appeal Br. 11.

We have reviewed Exhibits 6, 9, and 10, each of which describes success with Xience. However, as discussed above, it is not evident from these articles that the success and praise is a result of the claimed invention, rather than and unclaimed feature such as the drug or stent design. Exhibit 10, for example, compares Xience containing the everolimus drug in its coating with a paclitaxel stent. The article asks "'Should we abandon paclitaxel-eluting stents in favor of second-generation everolimus-eluting stents on the basis of the results of [this] study'," indicating that, at least in this case, the praise and success may be related to the everolimus drug.

SUMMARY

After considering the evidence in this record, including the evidence of secondary considerations and the declarations, we conclude that a preponderance of the evidence supports the Examiner's determination that claims 1 and 19 are unpatentable under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Tuch, Tu, and Lo. Dependent claims 2–17 and 20–23 were not argued separately. We affirm the rejection of these claims for the reasons given by the Examiner.

TIME PERIOD FOR RESPONSE

In accordance with 37 C.F.R. § 41.79(a)(1), the "[p]arties to the appeal may file a request for rehearing of the decision within one month of the date of: . . . [t]he original decision of the Board under § 41.77(a)." A request for rehearing must be in compliance with 37 C.F.R. § 41.79(b). Comments in opposition to the

request and additional requests for rehearing must be in accordance with 37 C.F.R. § 41.79(c) & (d), respectively. Under 37 C.F.R. § 41.79(e), the times for requesting rehearing under paragraph (a) of this section, for requesting further rehearing under paragraph (d) of this section, and for submitting comments under paragraph (c) of this section may not be extended.

An appeal to the United States Court of Appeals for the Federal Circuit under 35 U.S.C. §§ 141–144 and 315 and 37 C.F.R. § 1.983 for an *inter partes* reexamination proceeding "commenced" on or after November 2, 2002 may not be taken "until all parties' rights to request rehearing have been exhausted, at which time the decision of the Board is final and appealable by any party to the appeal to the Board." 37 C.F.R. § 41.81. *See also* MPEP § 2682 (8th ed., Rev. 7, July 2008).

In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. See 37 C.F.R. §§ 90.1 and 1.983.

AFFIRMED

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